PATENT
Attorney Docket No. **VARD-07989**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Sherry Leonard *et al.*
Serial No.: 10/723,940 Group No.: 1649
Filed: 11/26/2003 Examiner: Standley, S.H.
Entitled: **Promoter Variants of the Alpha-7 Nicotinic Acetylcholine Receptor**

INFORMATION DISCLOSURE STATEMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: March 7, 2006 By: Christine A. Lekutis

Dear Sir:

The citations listed below, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. § 1.56 and § 1.97. The Examiner is requested to make these citations of official record in this application.

Copies of the references listed as 1-14 on the enclosed PTO-1449 are **not** provided as Applicants are no longer required to provide copies of U.S. patents and published applications. In addition, copies of the citations listed as references 15-189 and 192-208 on the enclosed PTO-1449 are **not** provided since they were previously submitted to the Office in the earlier U.S. Application No. 08/956,518, filed on October 23, 1997 (Our File No. VARD-03042), to which priority is claimed. In particular, the citations listed as references 15-189 and 192-208 on the attached PTO-1449 were supplied to the Office in an Information Disclosure Statement (IDS) dated April 2, 1999 (and again in an IDS dated May 13, 2002).

The following printed publications are referred to in the body of the specification:

- U.S. Patent No. 4,650,764 to Temin *et al.* (1987);

- U.S. Patent No. 4,683,195 to Mullis (1987);
- U.S. Patent No. 4,683,202 to Mullis (1987);
- U.S. Patent No. 4,861,719 to Miller (1989);
- U.S. Patent No. 4,946,778 to Ladner *et al.* (1990);
- U.S. Patent No. 4,965,188 to Mullis (1990);
- U.S. Patent No. 4,980,289 to Temin *et al.* (1990);
- U.S. Patent No. 5,124,263 to Temin *et al.* (1992);
- U.S. Patent No. 5,322,770 to Gelfand (1994);
- U.S. Patent No. 5,399,346 to Anderson *et al.* (1995);
- U.S. Patent No. 5,459,127 to Felgner *et al.* (1995);
- U.S. Patent No. 5,580,859 to Felgner *et al.* (1996)
- U.S. Patent No. 5,589,466 to Felgner *et al.* (1996);
- European Patent No. EP 0178220 (1986):
- European Published Application No. EP 0453243 (1991);
- WIPO Publication No. WO 89/07150 (1989);
- WIPO Publication No. WO 90/02806 (1990);
- WIPO Publication No. WO 90/13678 (1990);
- WIPO Publication No. WO 92/05263 (1992);
- WIPO Publication No. WO 93/03367 (1993);
- WIPO Publication No. WO 94/21807 (1994);
- WIPO Publication No. WO 94/26914 (1994):
- WIPO Publication No. WO 95/02697 (1995):
- WIPO Publication No. WO 95/07358 (1995):
- WIPO Publication No. WO 95/18863 (1995);
- WIPO Publication No. WO 95/21931 (1995);
- WIPO Publication No. WO 96/15244 (1996);
- WIPO Publication No. WO 96/17823 (1996);
- WIPO Publication No. WO 96/25508 (1996);
- Adler *et al.*, " Normalization by Nicotine of Deficient Auditory Sensory Gating in the Relatives of Schizophrenics," *Biol. Psych.* 32: 607-616 (1992);

- Adler *et al.*, "Normalization of Auditory Physiology by Cigarette Smoking in Schizophrenic Patients," *Am. J. Psychol.* 150: 1856-1861 (1993);
- Adler *et al.*, "Neurophysiological Studies of Sensory Gating in Rats: Effects of Amphetamine, Phencyclidine, and Haloperidol," *Biol. Psychiat.* 21: 787-798 (1986);
- Adler *et al.*, "Neurophysiological Evidence for a Defect in Neuronal Mechanisms Involved in Sensory Gating in Schizophrenia," *Biol. Psychiat.* 17: 639-654 (1982);
- Albertsen *et al.*, "Construction and characterization of a yeast artificial chromosome library containing seven haploid human genome equivalents," *Proc. Natl. Acad. Sci.* 87: 4256-4260 (1990);
- Alkondon and Albuquerque, "Diversity of Nicotinic Acetylcholine Receptors in Rat Hippocampal Neurons. I. Pharmacological and Functional Evidence for District Structural Subtypes," *J. Pharm. Ex. Ther.* 265: 1455-1473 (1993);
- Amar *et al.*, "Agonist pharmacology of the neuronal α7 nicotinic receptor expressed in *Xenopus* oocytes," *FEBS* 327: 284-288 (1993);
- Anderson and Young, "Quantitative Filter Hybridization," in *Nucleic Acid Hybridization A Practical Approach*, Hames and Higgins (eds.), pp. 73-109, IRL Press (1985);
- Barnes, "PCR Amplification of up to 35-kb DNA with high fidelity and high yield from λ bacteriophage templates," *Proc. Natl. Acad. Sci. U.S.A.* 91: 2216-2220 (1994);
- Beard *et al.*, "Transcription Mapping of Mouse Adenovirus Type 1 Early Region 3," *Virology*, pp. 75-81 (1990);
- Beeson *et al.*, "The human muscle nicotinic acetylcholine receptor α-subunit exists as two isoforms: a novel exon," *EMBO J.* 9: 2101-2106 (1990);
- Bender *et al.*, "Evidence that the Packaging Signal of Moloney Murine Leukemia Virus Extends into the *gag* Region," *J. Virol.* 61: 1639-1646 (1987);
- Bernstein *et al.*, "Gene Transfer with Retrovirus Vectors," *Genet. Eng.* 7: 235-261 (1985);
- Bessis *et al.*, "Negative regulatory elements upstream of a novel exon of the neuronal nicotinic acetylcholine receptor of α2 subunit gene," *Nucl. Acids Res.* 21: 2185-2192 (1993);

- Bickford-Wimer *et al.*, "Auditory Sensory Gating in Hippocampal Neurons: A Model System in the Rat," *Biol. Psychiat.* 27: 183-192 (1990);
- Bickford and Wear, "Restoration of sensory gating of auditory evoked response by nicotine in fimbria-fornix lesioned rats," *Brain Res.* 705: 235-240 (1995);
- Biedler *et al.*, "Multiple Neurotransmitter Synthesis by Human Neuroblastoma Cell Lines and Clones," *Cancer Res.* 38: 3751-3757 (1978);
- Blount and Merlie, "Mutational Analysis of Muscle Nicotinic Acetylcholine Receptor Subunit Assembly," *J. Cell Biol.* 111: 2613-2622 (1990);
- Boshart *et al.*, "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," *Cell* 41:521-530 (1985);
- Boutros and Overall, "Replication and Extension of P50 Findings in Schizophrenia," *Clin. Electroencephalog.* 22: 40-45 (1991);
- Braff *et al.*, "Gating and Habituation of the Startle Reflex in Schizophrenic Patients," *Arch. Gen. Psychiat.* 49: 206-215 (1992);
- Breier *et al.*, "National Institute of Mental Health Longitudinal Study of Chronic Schizophrenia, Prognosis and Predictors of Outcome," *Arch. Gen. Psychiat.*, 48: 239-246 (1991);
- Brownstein *et al.*, "Isolation of Single-Copy Human Genes from a Library of Yeast Artificial Chromosome Clones," *Science* 244: 1348-1351 (1989);
- Burke *et al.*, "Cloning of Large Segments of Exogenous DNA into Yeast by Means of Artificial Chromosome Vectors," *Science* 236: 806-812 (1987);
- Calzolari *et al.*, "Psychiatric Disorder in a Familial 15;18 Translocation and Sublocalization of Myelin Basic Protein to 18q22.3," *Am. J. Med. Genet.* 67: 154-161 (1996);
- Cameron *et al.*, "Dendritic Cells Exposed to Human Immunodeficiency Virus Type-1 Transmit a Vigorous Cytophathic Infection to $CD4^+$ T Cells," *Science* 257: 383-387 (1992);
- Casaubon *et al.*, "The Gene Responsible for a Severe Form of Peripheral Neuropathy and Agenesis of the Corpus Callosum Maps to Chromosome 15q," *Am. J. Hum. Genet.* 58: 28-34 (1996);

- Chamberlin *et al.*, "New RNA Polymerase from *Escherichia coli* infected with Bacteriophage T7," *Nature* 228:227-231 (1970);
- Chomczynski and Sacchi, "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction," *Anal. Biochem.* 162: 156-159 (1987);
- Chumakov *et al.*, "Continuum of overlapping clones spanning the entire human chromosome 21q," *Nature* 359: 380-386 (1992);
- Clarke, "Prader-Willi Syndrome and Psychoses," *Brit. J. Psychiat.* 163: 680-684 (1993);
- Cole *et al.*, "The EBV-Hybridoma Technique and its Application to Human Lung Cancer," in *Monoclonal Antibodies and Cancer Therapy*, Reisfeld *et al.* (eds.), pp. 77-96, Alan R. Liss, Inc. (1985);
- Conti-Tronconi *et al.*, "Brain and muscle nicotinic acetylcholine receptors are different but homologous proteins," *Proc. Natl. Acad. Sci. U.S.A.* 82: 5208-5212 (1985);
- Coon *et al.*, "Search for Mutations in the β1 $GABA_A$ Receptor Subunit Gene in Patients with Schizophrenia," *Am. J. Med. Genet.* 54: 12-20 (1994);
- Coon *et al.*, "Use of a Neurophysiological Trait in Linkage Analysis of Schizophrenia," *Biol. Psychiat.* 34: 277-289 (1993);
- Cooper *et al.*, "Pentameric structure and subunit stoichiometry of a neuronal nicotinic acetylcholine receptor," *Nature* 350: 235-238 (1991);
- Cote *et al.*, "Generation of human monoclonal antibodies reactive with cellular antigens," *Proc. Natl. Acad. Sci. U.S.A.* 80: 2026-2030 (1983);
- Couturier *et al.*, "A Neuronal Nicotinic Acetylcholine Receptor Subunit (α7) Is Developmentally Regulated and Forms a Homo-Oligomeric Channel Blocked by α-BTX," *Neuron* 5: 847-856 (1990);
- Cullum *et al.*, "Neurophysiological and neuropsychological evidence for attentional dysfunction in schizophrenia," *Schizophrenia Res.* 10: 131-141 (1993);
- Curiel *et al.*, "High-Efficiency Gene Transfer Mediated by Adenovirus Coupled to DNA-Polylysine Complexes," *Hum. Gene Ther.* 3: 147-154 (1992);

- De Amicis *et al.*, "Reaction Time Crossover as a Marker of Schizophrenia and of Higher Functioning," *J. Nerv. Ment. Dis.* 174: 177-179 (1986);
- deLeon *et al.*, "Schizophrenia and Smoking: An Epidemiological Survey in a State Hospital," *Am. J. Psychiat.* 152: 453-455 (1995);
- Den-Dunnen *et al.*, "Topography of the Duchenne Muscular Dystrophy (DMD) Gene: FIGE and cDNA Analysis of 194 Cases Reveals 115 Deletions and 13 Duplications," *Am. J. Hum. Genet.* 45: 835-847 (1989);
- Deneris *et al.*, "Genes Encoding Neuronal Nicotinic Acetylcholine Receptors," *Clin. Chem.* 35: 731-737 (1989);
- Dijkema *et al.*, "Cloning and expression of the chromosomal immune interferon gene of the rat," *EMBO J.* 4:761-767 (1985);
- Dominguez del Toro *et al.*, "Immunocytochemical Localization of the α7 Subunit of the Nicotinic Acetylcholine Receptor in the Rat Central Nervous System," *J. Comp. Neurol.* 349: 325-342 (1994);
- Dracopoli *et al.*, *Current Protocols in Human Genetics*, John Wiley & Sons, Inc., New York, New York (1994) not provided;
- Eaton, "Epidemiology of Schizophrenia," *Epidemiol. Rev.* 7: 105-126 (1985);
- Elgoyhen *et al.*, "α9: An Acetylcholine Receptor with Novel Pharmacological Properties Expressed in Rat Cochlear Hair Cells," *Cell* 79: 705-715 (1994);
- Erlich (ed.), *PCR Technology*, Stockton Press (1989);
- Endicott and Spitzer, "A Diagnostic Interview, The Schedule for Affective Disorders and Schizophrenia," *Arch. Gen. Psychiat.* 35: 837-844 (1978);
- Erwin *et al.*, "Midlatency Auditory Evoked Responses in Schizophrenia," *Biol. Psychiat.* 30: 430-442 (1991);
- Felgner and Ringold, "Cationic liposome-mediated transfection," *Nature* 337: 387-388 (1989);
- Felgner *et al.*, "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," *Proc. Natl. Acad. Sci. U.S.A.* 84: 7413-7417 (1987);

- Freedman *et al.*, "α-Bungarotoxin Binding to Hippocampal Interneurons: Immunocytochemical Characterization and Effects on Growth Factor Expression," *J. Neurosci.* 13: 1965-1975 (1993);
- Freedman *et al.*, "Elementary neuronal dysfunctions in schizophrenia," *Schiz. Res.* 4: 233-243 (1991);
- Freedman *et al.*, "Schizophrenia and Nicotinic Receptors," *Harvard Rev. Psychiat.* 2: 179-192 (1994);
- Freedman *et al.*, "Evidence in Postmortem Brain Tissue for Decreased Numbers in Hippocampal Nicotinic Receptors in Schizophrenia," *Biol. Psychiat.* 38: 22-33 (1995);
- Frohman, *Amplifications* 5: 11 (1990) not provided;
- Galzi *et al.*, "Functional Architecture of the Nicotinic Acetylcholine Receptor: From Electric Organ to Brain," *Ann. Rev. Pharmacol.* 31: 37-72 (1991);
- Goff *et al.*, "Cigarette Smoking in Schizophrenia: Relationship to Psychopathology and Medication Side Effects," *Am. J. Psychiat.* 149: 1189-1194 (1992);
- Goff *et al.*, "Neural Origins of Long Latency Evoked Potentials Recorded from the Depth and from the Cortical Surface of the Brain in Man," *Prog. Clin. Neurophysiol.* 7: 126-145 (1980);
- Goldman *et al.*, "Members of a Nicotinic Acetylcholine Receptor Gene Family Are Expressed in Different Regions of the Mammalian Central Nervous System," *Cell* 48: 965-973 (1987);
- Gorman *et al.*, "The Rous sarcoma virus long terminal repeat is a strong promoter when introduced into a variety of eukaryotic cells by DNA-mediated transfection," *Proc. Natl. Acad. Sci. USA* 79: 6777-6781 (1982);
- Graham and van der Eb, "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA," *Virology* 52: 456-467 (1973);
- Green, "Biochemical Mechanisms of Constitutive and Regulated Pre-mRNA Splicing," *Ann. Rev. Cell. Biol.* 7: 559-599 (1991);

- Griffith *et al.*, "Effects of sound intensity on a midlatency evoked response to repeated auditory stimuli in schizophrenic and normal subjects," *Psychophysiology* 32: 460-466 (1995);
- Hamera *et al.*, "Alcohol, Cannabis, Nicotine, and Caffeine Use and Symptom Distress in Schizophrenia," *J. Nerv. Mental Dis.* 183: 559-565 (1995);
- Harlow and Lane, *Antibodies: A Laboratory Manual*, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York;
- Hershman *et al.*, "$GABA_B$ antagonists diminish the inhibitory gating of auditory response in the rat hippocampus," *Neurosci. Lett.* 190: 133-136 (1995);
- Holzman *et al.*, "A Single Dominant Gene Can Account for Eye Tracking Dysfunctions and Schizophrenia in Offspring of Discordant Twins," *Arch. Gen. Psychiat.* 45: 641-647 (1988);
- Hu and Worton, "Partial Gene Duplication as a Cause of Human Disease," *Hum. Mutat.* 1: 3-12 (1992);
- Huse *et al.*, "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda," *Science* 246: 1275-1281 (1989);
- Hyman, "Schizophrenia," in *Scientific American Medicine*, 13 VII: 1-5, Dale and Federman (eds.), New York, New York (1994);
- Judd *et al.*, "Sensory Gating Deficits in Schizophrenia: New Results," *Am. J. Psychiat.* 149: 488-493 (1992);
- Kacian *et al.*, "A Replicating RNA Molecule Suitable for a Detailed Analysis of Extracellular Evolution and Replication," *Proc. Natl. Acad. Sci. USA* 69: 3038-3042 (1972);
- Kaplitt *et al.*, "Expression of a Functional Foreign Gene in Adult Mammalian Brain following *in Vivo* Transfer via a Herpes Simplex Virus Type 1 Defective Viral Vector," *Mol. Cell. Neurosci.* 2: 320-330 (1991);
- Kim *et al.*, "Use of the human elongation factor 1α promoter as a versatile and efficient expression system," *Gene* 91:217-223 (1990);
- Kohler and Milstein, "Continuous cultures of fused cells secreting antibody of predefined specificity," *Nature* 256: 495-497 (1975);

- Kozbor *et al.*, "The production of monoclonal antibodies from human lymphocytes," *Immun. Today* 4: 72-79 (1983);
- Kruglyak *et al.*, "Parametric and Nonparametric Linkage Analysis: A Unified Multipoint Approach," *Am. J. Hum. Genet.* 58: 1347-1363 (1996);
- Kuo *et al.*, "Efficient Gene Transfer Into Primary Murine Lymphocytes Obviating the Need for Drug Selection," *Blood* 82: 845-852 (1993);
- Lamond, "The Spliceosome," *BioEssays* 15: 595-603 (1993);
- La Salle *et al.*, "An Adenovirus Vector for Gene Transfer into Neurons and Glia in the Brain," *Science* 259: 988-990 (1993);
- Lathrop *et al.*, "Strategies for multilocus linkage analysis in humans," *Proc. Natl. Acad. Sci. U.S.A.* 81: 3443-3446 (1984);
- Lebkowski *et al.*, "Adeno-Associated Virus: a Vector System for Efficient Introduction and Integration of DNA into a Variety of Mammalian Cell Types," *Mol. Cell. Biol.* 8: 3988-3996 (1988);
- Lehrman *et al.*, "Duplication of Seven Exons in LDL Receptor Gene Caused by Alu-Alu Recombination in a Subject with Familial Hypercholesterolemia," *Cell* 48: 827-835 (1987);
- Lindstrom *et al.*, "Neuronal Nicotinic Receptor Subtypes," *Ann. NY Acad. Sci.* 757: 100-116 (1996);
- Lukas and Bencherif, "Heterogeneity and Regulation of Nicotinic Acetylcholine Receptors," *Int. Rev. Neurobiol.* 34: 25-131 (1992);
- Luntz-Leybman *et al.*, "Cholinergic gating of response to auditory stimuli in rat hippocampus," *Brain. Res.* 587: 130-136 (1992);
- Machy *et al.*, "Gene transfer from targeted liposomes to specific lymphoid cells by electroporation," *Proc. Natl. Acad. Sci. U.S.A.* 85: 8027-8031 (1988);
- Mäkelä *et al.*, "Whole-head mapping of middle-latency auditory evoked magnetic fields," *Electroencephalogr. Clin. Neurophysiol.* 92: 414-421 (1994);
- Maniatis *et al.*, "Regulation of Inducible and Tissue-Specific Gene Expression," *Science* 236: 1237-1244 (1987);

- Mann *et al.*, "Construction of a Retrovirus Packaging Mutant and Its Use to Produce Helper-Free Defective Retrovirus," *Cell* 33: 153-159 (1983);
- Markowitz *et al.*, "A Safe Packaging Line for Gene Transfer: Separating Viral Genes on Two Different Plasmids," *J. Virol.* 62: 1120-1124 (1988);
- Marks and Collins, "Characterization of Nicotine Binding in Mouse Brain and Comparison with the Binding of α-Bungarotoxin and Quinuclidinyl Benzilate," *Mol. Pharmacol.* 22: 554 (1982);
- Marks *et al.*, "Nicotinic Binding Sites in Rat and Mouse Brain: Comparison of Acetylcholine, Nicotine, and α-Bungarotoxin," *Mol. Pharmacol.* 30: 427-437 (1986);
- Matter-Sadzinski *et al.*, "Neuronal specificity of the α7 nicotinic acetylcholine receptor promoter develops during morphogenesis of the central nervous system," *EMBO J.* 11: 4529-4538 (1992);
- Maue *et al.*, "Neuron-Specific Expression of the Rat Brain Type II Sodium Channel Gene Is Directed by Upstream Regulatory Elements," *Neuron* 4: 223-231 (1990);
- Melissari *et al.*, "Mitral valve prolapse in a case of Marfan syndrome with congenital cardiac disease, chronic obstructive pulmonary disease and schizophrenia," *Pathologica* 87: 78-81 (1995);
- Miller *et al.*, "A simple salting out procedure for extracting DNA from human nucleated cells," *Nucl. Acids Res.* 16: 1215 (1988);
- Miller and Rosman, "Improved Retroviral Vectors for Gene Transfer and Expression," *BioTechniques* 7: 980-990 (1992);
- Miller and Freeman, "The Activity of Hippocampal Interneurons and Pyramidal Cells During The Response of the Hippocampus to Repeated Auditory Stimuli," *Neurosci.* 69: 371-381 (1995);
- Mizushima and Nagata, "pEF-BOS, a powerful mammalian expression vector," *Nucl. Acids. Res.* 18:5322 (1990);
- Nagamoto *et al.*, "Sensory Gating in Schizophrenics and Normal Controls: Effects of Changing Stimulation Interval," *Biol. Psychiat.* 25: 549-561 (1989);
- Nagamoto *et al.*, "Gating of Auditory P50 in Schizophrenics: Unique Effects of Clozapine," *Biol. Psychiat.* 40: 181-188 (1996);

- Newland *et al.*, "Functional and non-functional isoforms of the human muscle acetylcholine receptor," *J. Physiol.* 489: 767-778 (1995);
- Nielsen *et al.*, "Peptide nucleic acids (PNAs): Potential anti-sense and anti-gene agents," *Anticancer Drug Des.* 8:53-63 (1993);
- Orr-Urtreger *et al.*, "Cloning and Mapping of the Mouse α7-Neuronal Nicotinic Acetylcholine Receptor," *Genomics* 26: 399-402 (1995);
- Ott, *Analysis of Human Genetic Linkage*, Johns Hopkins University Press, Baltimore (1991);
- Ott, "Computer-simulation methods in human linkage analysis," *Proc. Natl. Acad. Sci. U.S.A.* 86: 4175-2178 (1989);
- Patrick *et al.*, "Molecular Biology of Nicotinic Acetylcholine Receptors," *Ann. NY Acad. Sci.* 505: 194 (1987);
- Pauly *et al.*, "Glucocorticoid Regulation of Sensitivity to Nicotine," in *The Biology of Nicotine: Current Research Issues*, Lippiello et al. (eds.), pp. 121-139, Raven Press, New York (1992);
- Peng *et al.*, "Human α7 Acetylcholine Receptor: Cloning of the α7 Subunit from the SH-SY5Y Cell Line and Determination of Pharmacological Properties of Native Receptors and Functional α7 Homomers Expressed in *Xenopus* Oocytes," *Mol. Pharm.* 45: 546-554 (1994);
- Pulver *et al.*, "Follow-Up of a Report of a Potential Linkage for Schizophrenia on Chromosome 22q12-q13.1: Part 2," *Am. J. Med. Genet.* 54: 44-50 (1994);
- Risch, "Genetic Linkage and Complex Diseases, With Special Reference to Psychiatric Disorders," *Genet. Epidemiol.* 7: 3-16 (1990);
- Rollins *et al.*, "Cellular Localization of α-Bungarotoxin Binding and α7 mRNA in the Hippocampus Related to Auditory Gating in the Awake, Behaving Rat," *Soc. Neurosci. Abst.* 22: 1272 (1996);
- Saksela *et al.*, "Human immunodeficiency virus type 1 mRNA expression in peripheral blood cells predicts disease progression independently of the numbers of $CD4^+$ lymphocytes," *Proc. Natl. Acad. Sci. U.S.A.* 91: 1104-1108 (1994);

- Saksela *et al.*, "High Viral Load in Lymph Nodes and Latent Human Immunodeficiency Virus (HIV) in Peripheral Blood Cells of HIV-1 Infected Chimpanzees," *J. Virol.* 67: 7423-7427 (1993);
- Sambrook *et al.*, *Molecular Cloning: A Laboratory Manual*, 2nd ed., pp. 7.39-7.52, 9.31-9.58, 16.6-16.15, Cold Spring Laboratory Press, New York (1989);
- Samulski *et al.*, "A Recombinant Plasmid from Which an Infectious Adeno-Associated Virus Genome Can Be Excised *In Vitro* and Its Use To Study Viral Replication," *J. Virol.* 61: 3096-3101 (1987);
- Samulski *et al.*, "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression," *J. Virol.* 63: 3822-3828 (1989);
- Sauerwald *et al.*, "The 5'-Flanking Region of the Synapsin I Gene," *J. Biol. Chem.* 265: 14932-14937 (1990);
- Schmid, "Alu: Structure, Origin, Evolution, Significance and Function of One-Tenth of Human DNA," *Prog. Nucl. Acid Res.* 53: 283-319 (1996);
- Schoepfer *et al.*, "Brain α-Bungarotoxin Binding Protein cDNAs and MAbs Reveal Subtypes of This Branch of the Ligand-Gated Ion Channel Gene Superfamily," *Neuron* 5: 35-48 (1990);
- Séguéla *et al.*, "Molecular Cloning, Functional Properties, and Distribution of Rat Brain α7: A Nicotinic Cation Channel Highly Permeable to Calcium," *J. Neurosci.* 13: 596-604 (1993);
- Sham *et al.*, "Segregration analysis of complex phenotypes: an application to schizophrenia and auditory P300 latency," *Psychiat. Genet.* 4: 29-38 (1994);
- Siegel *et al.*, "Deficits in Sensory Gating in Schizophrenic Patients and Their Relatives, Evidence Obtained With Auditory Evoked Responses," *Arch. Gen. Psychiat.* 41: 607-612 (1984);
- Silverman *et al.*, "Evidence of a Locus for Schizophrenia and Related Disorders on the Short Arm of Chromosome 5 in a Large Pedigree," *Am. J. Med. Genet.* 67: 162-171 (1996);

- Sirota *et al.*, "Schizophrenia and Marfan Syndrome," *Br. J. Psychiat.* 157: 433-436 (1990);
- Spitzer *et al.*, "Research Diagnostic Criteria, Rationale and Reliability," *Arch. Gen. Psychiat.* 35: 773-782 (1978);
- Stratford-Perricaudet *et al.*, "Widespread Long-term Gene Transfer to Mouse Skeletal Muscles and Heart," *J. Clin. Invest.* 90: 626-630 (1992);
- Tsuang *et al.*, "Long-term Outcome of Major Psychoses I. Schizophrenia and Affective Disorders Compared with Psychiatrically Symptom-Free Surgical Conditions," *Arch. Gen. Psychiat.* 36: 1295-1301 (1979);
- Tsuang *et al.*, "Genotypes, Phenotypes, and the Brain, A Search for Connections in Schizophrenia," *Brit. J. Psychiat.* 163: 299-307 (1993);
- Uetsuki *et al.*, "Isolation and Characterization of the Human Chromosomal Gene for Polypeptide Chain Elongation Factor-1α," *J. Biol. Chem.* 264:5791 (1989);
- Ulmer *et al.*, "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," *Science* 259: 1745-1748 (1993);
- Vinogradova *et al.*, "Do Semantic Priming Effects Correlate with Sensory Gating in Schizophrenia," *Biol. Psychiat.* 39: 821-824 (1996);
- Vinogradova, in *The Hippocampus 2: Neurophysiology and Behavior*, Issacson and Pribram (eds.), pp. 3-69, Plenum Press, New York, New York (1975);
- von Heijne, "A new method for predicting signal sequence cleavage sites," *Nucl. Acids Res.* 14: 4683-4690 (1986);
- Voss *et al.*, "The role of enhancers in the regulation of cell-type-specific transcriptional control," *Trends Biochem. Sci.* 11:287-289 (1986);
- Wada *et al.*, "Distribution of Alpha2, Alpha3, Alpha4, and Beta2 Neuronal Nicotinic Receptor Subunit mRNAs in the Central Nervous System: A Hybridization Histochemical Study in the Rat," *J. Compar. Neurol.* 284: 314-335 (1989);
- Waldo *et al.*, "Codistribution of a Sensory Gating Deficit and Schizophrenia in Multi-affected Families," *Psychiat. Res.* 39: 257-268 (1991);
- Waldo *et al.*, "Auditory sensory gating, hippocampal volume, and catecholamine metabolism in schizophrenics and their siblings," *Schizophr. Res.* 12: 93-106 (1991);

- Wang *et al.*, "Evidence for a susceptibility locus for schizophrenia on chromosome 6pter-p22," *Nature Genet.* 10: 41-46 (1995);
- Williams *et al.*, "Introduction of foreign genes into tissues of living mice by DNA-coated microprojectiles," *Proc. Natl. Acad. Sci. U.S.A.* 88: 2726-2730 (1991);
- Wilson *et al.*, "Habituation of Human Limbic Neuronal Response to Sensory Stimulation," *Exp. Neurol.* 84: 74-97 (1984);
- Wilson *et al.*, "Hepatocyte-directed Gene Transfer in Vivo Leads to Transient Improvement of Hypercholesterolemia in Low Density Lipoprotein Receptor-deficient Rabbits," *J. Biol. Chem.* 267: 963-967 (1992);
- Wonnacott, "α-Bungarotoxin Binds to Low-Affinity Nicotine Binding Sites in Rat Brain," *J. Neurochem.* 47: 1706-1712 (1986);
- Wu and Wallace, "The Ligation Amplification Reaction (LAR) -- Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," *Genomics* 4:560-569 (1989);
- Wu and Wu, "Receptor-mediated Gene Delivery and Expression in Vivo," *J. Biol. Chem.* 263: 14621-14624 (1988);
- Wu and Wu, "Receptor-mediated *in Vitro* Gene Transformation by a Soluble DNA Carrier System," *J. Biol. Chem.* 262: 4429-4432 (1987); and
- Zhang *et al.*, "Neuronal Acetylcholine Receptors That Bind α-Bungarotoxin with High Affinity Function as Ligand-Gated Ion Channels," *Neuron* 12: 167-177 (1994).

In addition, Applicants have become aware of the following printed publications, which may be material to the examination of this application:

- Anand and Lindstrom, "Nucleotide sequence of the human nicotinic acetylcholine receptor β2 subunit gene," *Nuc. Acids Res.* 18: 4272 (1990);
- Chini *et al.*, "Molecular Cloning and Chromosomal Localization of the Human α7-Nicotinic Receptor Subunit Gene (CHRNA7)," *Genomics* 19: 379-381 (1994);
- Deneris *et al.*, "Primary Structure and Expression of β2: A Novel Subunit of Neuronal Nicotinic Acetylcholine Receptors," *Neuron* 1: 45-54 (1988);

- Doucette-Stamm *et al.*, "Cloning and Sequence of the Human α7 Nicotinic Acetylcholine Receptor," *Drug Dev. Res.* 30: 252-256 (1993);
- Fornasari *et al.*, "Molecular cloning of human neuronal nicotinic receptor α3-subunit," *Neurosci. Lett.* 111: 351-356 (1990);
- Fornasari *et al.*, "Structural and Functional Characterization of the Human α3 Nicotinic Subunit Gene Promoter," *Mol. Pharmacol.* 51: 250-261 (1997);
- Garcia-Guzman *et al.*, "α-Bungarotoxin-sensitive Nicotinic Receptors on Bovine Chromaffin Cells: Molecular Cloning, Functional Expression and Alternative Splicing of the α7 Subunit," *Eur. J. Neuorosci.* 7: 647-655 (1995);
- GenBank Accession No. X70297 (1993); and
- GenBank Accession No. Z58126.

Also included for the Examiner's convenience are the following publications in which the inventors are co-authors. These publications, while not prior art, have been included for the sake of completeness:

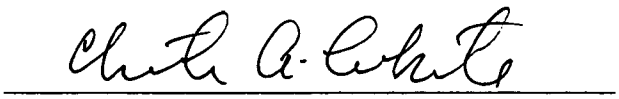
- Breese *et al.*, "Comparison of the Regional Expression of Nicotinic Acetylcholine Receptor α7 mRNA and [^{125}I]-α-bungarotoxin binding in Human Postmortem Brain," *J. Comp. Neurol.* 387: 385-398 (1997);
- Leonard *et al.*, "Linkage of a chromosome 15 locus to a neurophysiological deficit in schizophrenia," *Am. J. Human Genet.* 59: A225 (1996);
- Leonard *et al.*, "Genomic Structure of the Human α7 Neuronal Nicotinic Acetylcholine Receptor Subunit," *Abstracts, Society for Neuroscience*, 27th Annual Meeting, October 25-30 (1997);
- Freedman *et al.*, "Linkage of a neurophysiological deficit in schizophrenia to a chromosome 15 locus," *Proc. Natl. Acad. Sci. U.S.A.* 94: 587-592 (1997);
- Breese *et al.*, "Abnormal Regulation of High Affinity Nicotinic Receptor Binding in Schizophrenics," *Abstracts, Society for Neuroscience*, 27th Annual Meeting, October 25-30 (1997);

- Gault *et al.*, "Contig construction across the 15q14 schizophrenia linkage region and candidate gene characterization of the partially duplicated α7 nicotinic receptor," *Am. J. Human Genet.* 63: A249 (1998);
- Leonard *et al.*, "Additional evidence for a chromosome 15 locus in schizophrenia: Analysis of affected sibpairs from the NMH genetics initiative," *Am. J. Human Genet.* 63: A297 (1998);
- Zetterström *et al.*, "Polymorphisms at the Calcitonin/CGRP-α Gene Locus: Investigation of Possible Associations with Neurological or Psychiatric Disease," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998);
- Drebing *et al.*, "Expression of the Human α7 Neuronal Nicotinic Acetylcholine Receptor and a Partial Gene Duplication," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998);
- Leonard *et al.*, "Genomic Organization and Partial Duplication of the Human α7 Neuronal Nicotinic Acetylcholine Receptor Subunit Gene," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998);
- Dudek *et al.*, "Expression in Human Brain of Novel Exons Associated with a Partial Duplication of the α7 Neuronal Nicotinic Receptor," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998);
- Breese *et al.*, "Abnormal Regulation of the High Affinity Nicotinic Receptors in Schizophrenia," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998);
- Lee *et al.*, "The Effect of Nicotine and Haloperidol on High Affinity Nicotinic Receptors and Dopamine D2 Receptors in the Rat Brain," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998)
- Adler *et al.*, "Schizophrenia, Sensory Gating, and Nicotinic Receptors," *Schizophrenia Bulletin* 24: 189-202 (1998);
- Leonard *et al.*, "Further Investigation of a Chromosome 15 Locus in Schizophrenia: Analysis of Affected Sibpairs From the NIMH Genetics Initiative," *Am. J. Med. Genet.* 81: 308-312 (1998);

- Gault *et al.*, "Genomic Organization and Partial Duplication of the Human α7 Neuronal Nicotinic Acetylcholine Receptor Gene (CHRNA7), *Genomics* 52: 173-185 (1998);
- Leonard *et al.*, "Association of promoter variants in the alpha7 nicotinic acetylcholine receptor subunit gene with an inhibitory deficit found in schizophrenia," *Arch Gen Psychiatry*, 59:1085-1096 (2002);
- Gault *et al.*, "Comparison of polymorphisms in the alpha7 nicotinic receptor gene and its partial duplication in schizophrenic and control subjects," *Am J Med Genet B Neuropsychiatr Genet*, 123:39-49 (2003);
- Leonard, "Consequences of low levels of nicotinic acetylcholine receptors in schizophrenia for drug development, *Drug Development Research,* 60:127-136 (2003); and
- Mexal *et al.*, Differential modulation of gene expression in the NMDA postsynaptic density of schizophrenic and control smokers," *Mol Brain Res*, 139:317-332 (2005).

This Information Disclosure Statement under 37 C.F.R. § 1.56 and § 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: March 7, 2006

By: 

Christine A. Lekutis
Registration No. 51,934

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
415.904.6500

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JU/

FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VARD-07989	Serial No.: 10/723,940
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)		Applicant: Sherry Leonard *et al.*	
(37 CFR § 1.98(b))		Filing Date: 11/26/2003	Group Art Unit: 1649

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	4,650,764	03/17/87	Temin *et al.*			03/26/84
	2	4,683,195	07/28/87	Mullis *et al.*			02/07/86
	3	4,683,202	07/28/87	Mullis			10/25/85
	4	4,861,719	08/29/89	Miller			04/25/86
	5	4,946,778	08/7/90	Ladner *et al.*			01/19/89
	6	4,965,188	10/23/90	Mullis *et al.*			06/17/87
	7	4,980,289	12/25/90	Temin *et al.*			04/27/87
	8	5,124,263	06/23/92	Temin *et al.*			01/12/89
	9	5,322,770	06/21/94	Gelfand			12/22/89
	10	5,399,346	03/21/95	Anderson *et al.*			03/30/94
	11	5,459,127	10/17/95	Felgner *et al.*			09/16/93
	12	5,580,859	12/03/96	Felgner *et al.*			03/18/94
	13	5,589,466	12/31/96	Felgner *et al.*			01/26/95
	14	5,837,489	11/17/98	Elliott *et al.*			06/05/95

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	15	WO 96/25508	08/22/96	PCT				
	16	WO 96/17823	06/13/96	PCT				
	17	WO 95/21931	08/17/95	PCT				
	18	WO 95/18863	07/13/95	PCT				
	19	WO 96/15244	05/23/96	PCT				
	20	WO 95/07358	03/16/95	PCT				
	21	WO 95/02697	01/26/95	PCT				
	22	WO 94/26914	11/24/94	PCT				
	23	WO 94/21807	09/29/94	PCT				
	24	WO 93/03367	02/18/93	PCT				
	25	WO 92/05263	04/02/92	PCT				
	26	WO 90/02806	03/22/90	PCT				
	27	WO 90/13678	11/15/90	PCT				
	28	WO 89/07150	08/10/89	PCT				
	29	EP 0453243A2	10/23/91	European Patent Office				
	30	EP 0178220 B1	04/16/86	European Patent Office				

Examiner:	/John Ulm/	Date Considered:	04/03/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JU/

FORM PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VARD-07989	Serial No.: 10/723,940
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))	Applicant: Sherry Leonard *et al.*	
	Filing Date: 11/26/2003	Group Art Unit: 1649

		OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)
	31	Adler *et al.*, " Normalization by Nicotine of Deficient Auditory Sensory Gating in the Relatives of Schizophrenics," *Biol. Psych.* 32: 607-616 (1992)
	32	Adler *et al.*, "Normalization of Auditory Physiology by Cigarette Smoking in Schizophrenic Patients," *Am. J. Psychol.* 150: 1856-1861 (1993)
	33	Adler *et al.*, "Neurophysiological Studies of Sensory Gating in Rats: Effects of Amphetamine, Phencyclidine, and Haloperidol," *Biol. Psychiat.* 21: 787-798 (1986)
	34	Adler *et al.*, "Neurophysiological Evidence for a Defect in Neuronal Mechanisms Involved in Sensory Gating in Schizophrenia," *Biol. Psychiat.* 17: 639-654 (1982)
	35	Albertsen *et al.*, "Construction and characterization of a yeast artificial chromosome library containing seven haploid human genome equivalents," *Proc. Natl. Acad. Sci.* 87: 4256-4260 (1990)
	36	Alkondon and Albuquerque, "Diversity of Nicotinic Acetylcholine Receptors in Rat Hippocampal Neurons. I. Pharmacological and Functional Evidence for District Structural Subtypes," *J. Pharm. Ex. Ther.* 265: 1455-1473 (1993)
	37	Amar *et al.*, "Agonist pharmacology of the neuronal α7 nicotinic receptor expressed in *Xenopus* oocytes," *FEBS* 327: 284-288 (1993)
	38	Anderson and Young, "Quantitative Filter Hybridization," in *Nucleic Acid Hybridization A Practical Approach*, Hames and Higgins (eds.), pp. 73-109, IRL Press (1985)
	39	Barnes, "PCR Amplification of up to 35-kb DNA with high fidelity and high yield from λ bacteriophage templates," *Proc. Natl. Acad. Sci. U.S.A.* 91: 2216-2220 (1994)
	40	Beard *et al.*, "Transcription Mapping of Mouse Adenovirus Type 1 Early Region 3," *Virology*, pp. 75-81 (1990)
	41	Beeson *et al.*, "The human muscle nicotinic acetylcholine receptor α-subunit exists as two isoforms: a novel exon," *EMBO J.* 9: 2101-2106 (1990)
	42	Bender *et al.*, "Evidence that the Packaging Signal of Moloney Murine Leukemia Virus Extends into the *gag* Region," *J. Virol.* 61: 1639-1646 (1987)
	43	Bernstein *et al.*, "Gene Transfer with Retrovirus Vectors," *Genet. Eng.* 7: 235-261 (1985)
	44	Bessis *et al.*, "Negative regulatory elements upstream of a novel exon of the neuronal nicotinic acetylcholine receptor of α2 subunit gene," *Nucl. Acids Res.* 21: 2185-2192 (1993)
	45	Bickford-Wimer *et al.*, "Auditory Sensory Gating in Hippocampal Neurons: A Model System in the Rat," *Biol. Psychiat.* 27: 183-192 (1990)
	46	Bickford and Wear, "Restoration of sensory gating of auditory evoked response by nicotine in fimbria-fornix lesioned rats," *Brain Res.* 705: 235-240 (1995)
	47	Biedler *et al.*, "Multiple Neurotransmitter Synthesis by Human Neuroblastoma Cell Lines and Clones," *Cancer Res.* 38: 3751-3757 (1978)
	48	Blount and Merlie, "Mutational Analysis of Muscle Nicotinic Acetylcholine Receptor Subunit Assembly," *J. Cell Biol.* 111: 2613-2622 (1990)
	49	Boshart *et al.*, "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," *Cell* 41:521-530 (1985)
	50	Boutros and Overall, "Replication and Extension of P50 Findings in Schizophrenia," *Clin. Electroencephalog.* 22: 40-45 (1991)
	51	Braff *et al.*, "Gating and Habituation of the Startle Reflex in Schizophrenic Patients," *Arch. Gen. Psychiat.* 49: 206-215 (1992)
	52	Breier *et al.*, "National Institute of Mental Health Longitudinal Study of Chronic Schizophrenia, Prognosis and Predictors of Outcome," *Arch. Gen. Psychiat.*, 48: 239-246 (1991)
	53	Brownstein *et al.*, "Isolation of Single-Copy Human Genes from a Library of Yeast Artificial Chromosome Clones," *Science* 244: 1348-1351 (1989)
	54	Burke *et al.*, "Cloning of Large Segments of Exogenous DNA into Yeast by Means of Artificial Chromosome Vectors," *Science* 236: 806-812 (1987)
	55	Calzolari *et al.*, "Psychiatric Disorder in a Familial 15;18 Translocation and Sublocalization of Myelin Basic Protein to 18q22.3," *Am. J. Med. Genet.* 67: 154-161 (1996)

Examiner:	/John Ulm/	04/03/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JU/

FORM PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VARD-07989	Serial No.: 10/723,940
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))	Applicant: Sherry Leonard *et al.*	
	Filing Date: 11/26/2003	Group Art Unit: 1649

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	56	Cameron *et al.*, "Dendritic Cells Exposed to Human Immunodeficiency Virus Type-1 Transmit a Vigorous Cytophathic Infection to $CD4^+$ T Cells," *Science* 257: 383-387 (1992)
	57	Casaubon *et al.*, "The Gene Responsible for a Severe Form of Peripheral Neuropathy and Agenesis of the Corpus Callosum Maps to Chromosome 15q," *Am. J. Hum. Genet.* 58: 28-34 (1996)
	58	Chamberlin *et al.*, "New RNA Polymerase from *Escherichia coli* infected with Bacteriophage T7," *Nature* 228:227-231 (1970)
	59	Chomczynski and Sacchi, "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction," *Anal. Biochem.* 162: 156-159 (1987)
	60	Chumakov *et al.*, "Continuum of overlapping clones spanning the entire human chromosome 21q," *Nature* 359: 380-386 (1992)
	61	Clarke, "Prader-Willi Syndrome and Psychoses," *Brit. J. Psychiat.* 163: 680-684 (1993)
	62	Cole *et al.*, "The EBV-Hybridoma Technique and its Application to Human Lung Cancer," in *Monoclonal Antibodies and Cancer Therapy*, Reisfeld *et al.* (eds.), pp. 77-96, Alan R. Liss, Inc. (1985)
	63	Conti-Tronconi *et al.*, "Brain and muscle nicotinic acetylcholine receptors are different but homologous proteins," *Proc. Natl. Acad. Sci. U.S.A.* 82: 5208-5212 (1985)
	64	Coon *et al.*, "Search for Mutations in the β1 $GABA_A$ Receptor Subunit Gene in Patients with Schizophrenia," *Am. J. Med. Genet.* 54: 12-20 (1994)
	65	Coon *et al.*, "Use of a Neurophysiological Trait in Linkage Analysis of Schizophrenia," *Biol. Psychiat.* 34: 277-289 (1993)
	66	Cooper *et al.*, "Pentameric structure and subunit stoichiometry of a neuronal nicotinic acetylcholine receptor," *Nature* 350: 235-238 (1991)
	67	Cote *et al.*, "Generation of human monoclonal antibodies reactive with cellular antigens," *Proc. Natl. Acad. Sci. U.S.A.* 80: 2026-2030 (1983)
	68	Couturier *et al.*, "A Neuronal Nicotinic Acetylcholine Receptor Subunit (α7) Is Developmentally Regulated and Forms a Homo-Oligomeric Channel Blocked by α-BTX," *Neuron* 5: 847-856 (1990)
	69	Cullum *et al.*, "Neurophysiological and neuropsychological evidence for attentional dysfunction in schizophrenia," *Schizophrenia Res.* 10: 131-141 (1993)
	70	Curiel *et al.*, "High-Efficiency Gene Transfer Mediated by Adenovirus Coupled to DNA-Polylysine Complexes," *Hum. Gene Ther.* 3: 147-154 (1992)
	71	De Amicis *et al.*, "Reaction Time Crossover as a Marker of Schizophrenia and of Higher Functioning," *J. Nerv. Ment. Dis.* 174: 177-179 (1986)
	72	deLeon *et al.*, "Schizophrenia and Smoking: An Epidemiological Survey in a State Hospital," *Am. J. Psychiat.* 152: 453-455 (1995)
	73	Den-Dunnen *et al.*, "Topography of the Duchenne Muscular Dystrophy (DMD) Gene: FIGE and cDNA Analysis of 194 Cases Reveals 115 Deletions and 13 Duplications," *Am. J. Hum. Genet.* 45: 835-847 (1989)
	74	Deneris *et al.*, "Genes Encoding Neuronal Nicotinic Acetylcholine Receptors," *Clin. Chem.* 35: 731-737 (1989)
	75	Dijkema *et al.*, "Cloning and expression of the chromosomal immune interferon gene of the rat," *EMBO J.* 4:761-767 (1985)
	76	Dominguez del Toro *et al.*, "Immunocytochemical Localization of the α7 Subunit of the Nicotinic Acetylcholine Receptor in the Rat Central Nervous System," *J. Comp. Neurol.* 349: 325-342 (1994)
	~~77~~	~~Dracopoli *et al.*, *Current Protocols in Human Genetics*, John Wiley & Sons, Inc., New York, New York (1994) not provided~~
	78	Eaton, "Epidemiology of Schizophrenia," *Epidemiol. Rev.* 7: 105-126 (1985)
	79	Elgoyhen *et al.*, "α9: An Acetylcholine Receptor with Novel Pharmacological Properties Expressed in Rat Cochlear Hair Cells," *Cell* 79: 705-715 (1994)
	80	Erlich (ed.), *PCR Technology*, Stockton Press (1989)

Examiner:	/John Ulm/	04/03/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JU/

FORM PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VARD-07989	Serial No.: 10/723,940
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))	Applicant: Sherry Leonard *et al.*	
	Filing Date: 11/26/2003	Group Art Unit: 1649

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	81	Endicott and Spitzer, "A Diagnostic Interview, The Schedule for Affective Disorders and Schizophrenia," *Arch. Gen. Psychiat.* 35: 837-844 (1978)
	82	Erwin *et al.*, "Midlatency Auditory Evoked Responses in Schizophrenia," *Biol. Psychiat.* 30: 430-442 (1991)
	83	Felgner and Ringold, "Cationic liposome-mediated transfection," *Nature* 337: 387-388 (1989)
	84	Felgner *et al.*, "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," *Proc. Natl. Acad. Sci. U.S.A.* 84: 7413-7417 (1987)
	85	Freedman *et al.*, "α-Bungarotoxin Binding to Hippocampal Interneurons: Immunocytochemical Characterization and Effects on Growth Factor Expression," *J. Neurosci.* 13: 1965-1975 (1993)
	86	Freedman *et al.*, "Elementary neuronal dysfunctions in schizophrenia," *Schiz. Res.* 4: 233-243 (1991)
	87	Freedman *et al.*, "Schizophrenia and Nicotinic Receptors," *Harvard Rev. Psychiat.* 2: 179-192 (1994)
	88	Freedman *et al.*, "Evidence in Postmortem Brain Tissue for Decreased Numbers in Hippocampal Nicotinic Receptors in Schizophrenia," *Biol. Psychiat.* 38: 22-33 (1995)
	~~89~~	~~Frohman, *Amplifications* 5: 11 (1990) not provided~~
	90	Galzi *et al.*, "Functional Architecture of the Nicotinic Acetylcholine Receptor: From Electric Organ to Brain," *Ann. Rev. Pharmacol.* 31: 37-72 (1991)
	91	Goff *et al.*, "Cigarette Smoking in Schizophrenia: Relationship to Psychopathology and Medication Side Effects," *Am. J. Psychiat.* 149: 1189-1194 (1992)
	92	Goff *et al.*, "Neural Origins of Long Latency Evoked Potentials Recorded from the Depth and from the Cortical Surface of the Brain in Man," *Prog. Clin. Neurophysiol.* 7: 126-145 (1980)
	93	Goldman *et al.*, "Members of a Nicotinic Acetylcholine Receptor Gene Family Are Expressed in Different Regions of the Mammalian Central Nervous System," *Cell* 48: 965-973 (1987)
	94	Gorman *et al.*, "The Rous sarcoma virus long terminal repeat is a strong promoter when introduced into a variety of eukaryotic cells by DNA-mediated transfection," *Proc. Natl. Acad. Sci. USA* 79: 6777-6781 (1982)
	95	Graham and van der Eb, "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA," *Virology* 52: 456-467 (1973)
	96	Green, "Biochemical Mechanisms of Constitutive and Regulated Pre-mRNA Splicing," *Ann. Rev. Cell. Biol.* 7: 559-599 (1991)
	97	Griffith *et al.*, "Effects of sound intensity on a midlatency evoked response to repeated auditory stimuli in schizophrenic and normal subjects," *Psychophysiology* 32: 460-466 (1995)
	98	Hamera *et al.*, "Alcohol, Cannabis, Nicotine, and Caffeine Use and Symptom Distress in Schizophrenia," *J. Nerv. Mental Dis.* 183: 559-565 (1995)
	~~99~~	~~Harlow and Lane, *Antibodies: A Laboratory Manual*, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York~~
	100	Hershman *et al.*, "$GABA_B$ antagonists diminish the inhibitory gating of auditory response in the rat hippocampus," *Neurosci. Lett.* 190: 133-136 (1995)
	101	Holzman *et al.*, "A Single Dominant Gene Can Account for Eye Tracking Dysfunctions and Schizophrenia in Offspring of Discordant Twins," *Arch. Gen. Psychiat.* 45: 641-647 (1988)
	102	Hu and Worton, "Partial Gene Duplication as a Cause of Human Disease," *Hum. Mutat.* 1: 3-12 (1992)
	103	Huse *et al.*, "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda," *Science* 246: 1275-1281 (1989)
	104	Hyman, "Schizophrenia," in *Scientific American Medicine*, 13 VII: 1-5, Dale and Federman (eds.), New York, New York (1994)
	105	Judd *et al.*, "Sensory Gating Deficits in Schizophrenia: New Results," *Am. J. Psychiat.* 149: 488-493 (1992)

Examiner: /John Ulm/	Date Considered: 04/03/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JU/

FORM PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VARD-07989	Serial No.: 10/723,940
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))	Applicant: Sherry Leonard *et al.*	
	Filing Date: 11/26/2003	Group Art Unit: 1649

		OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)
	106	Kacian *et al.*, "A Replicating RNA Molecule Suitable for a Detailed Analysis of Extracellular Evolution and Replication," *Proc. Natl. Acad. Sci. USA* 69: 3038-3042 (1972)
	107	Kaplitt *et al.*, "Expression of a Functional Foreign Gene in Adult Mammalian Brain following *in Vivo* Transfer via a Herpes Simplex Virus Type 1 Defective Viral Vector," *Mol. Cell. Neurosci.* 2: 320-330 (1991)
	108	Kim *et al.*, "Use of the human elongation factor 1α promoter as a versatile and efficient expression system," *Gene* 91:217-223 (1990)
	109	Kohler and Milstein, "Continuous cultures of fused cells secreting antibody of predefined specificity," *Nature* 256: 495-497 (1975)
	110	Kozbor *et al.*, "The production of monoclonal antibodies from human lymphocytes," *Immun. Today* 4: 72-79 (1983)
	111	Kruglyak *et al.*, "Parametric and Nonparametric Linkage Analysis: A Unified Multipoint Approach," *Am. J. Hum. Genet.* 58: 1347-1363 (1996)
	112	Kuo *et al.*, "Efficient Gene Transfer Into Primary Murine Lymphocytes Obviating the Need for Drug Selection," *Blood* 82: 845-852 (1993)
	113	Lamond, "The Spliceosome," *BioEssays* 15: 595-603 (1993)
	114	La Salle *et al.*, "An Adenovirus Vector for Gene Transfer into Neurons and Glia in the Brain," *Science* 259: 988-990 (1993)
	115	Lathrop *et al.*, "Strategies for multilocus linkage analysis in humans," *Proc. Natl. Acad. Sci. U.S.A.* 81: 3443-3446 (1984)
	116	Lebkowski *et al.*, "Adeno-Associated Virus: a Vector System for Efficient Introduction and Integration of DNA into a Variety of Mammalian Cell Types," *Mol. Cell. Biol.* 8: 3988-3996 (1988)
	117	Lehrman *et al.*, "Duplication of Seven Exons in LDL Receptor Gene Caused by Alu-Alu Recombination in a Subject with Familial Hypercholesterolemia," *Cell* 48: 827-835 (1987)
	118	Lindstrom *et al.*, "Neuronal Nicotinic Receptor Subtypes," *Ann. NY Acad. Sci.* 757: 100-116 (1996)
	119	Lukas and Bencherif, "Heterogeneity and Regulation of Nicotinic Acetylcholine Receptors," *Int. Rev. Neurobiol.* 34: 25-131 (1992)
	120	Luntz-Leybman *et al.*, "Cholinergic gating of response to auditory stimuli in rat hippocampus," *Brain. Res.* 587: 130-136 (1992)
	121	Machy *et al.*, "Gene transfer from targeted liposomes to specific lymphoid cells by electroporation," *Proc. Natl. Acad. Sci. U.S.A.* 85: 8027-8031 (1988)
	122	Mäkelä *et al.*, "Whole-head mapping of middle-latency auditory evoked magnetic fields," *Electroencephalogr. Clin. Neurophysiol.* 92: 414-421 (1994)
	123	Maniatis *et al.*, "Regulation of Inducible and Tissue-Specific Gene Expression," *Science* 236: 1237-1244 (1987)
	124	Mann *et al.*, "Construction of a Retrovirus Packaging Mutant and Its Use to Produce Helper-Free Defective Retrovirus," *Cell* 33: 153-159 (1983)
	125	Markowitz *et al.*, "A Safe Packaging Line for Gene Transfer: Separating Viral Genes on Two Different Plasmids," *J. Virol.* 62: 1120-1124 (1988)
	126	Marks and Collins, "Characterization of Nicotine Binding in Mouse Brain and Comparison with the Binding of α-Bungarotoxin and Quinuclidinyl Benzilate," *Mol. Pharmacol.* 22: 554 (1982)
	127	Marks *et al.*, "Nicotinic Binding Sites in Rat and Mouse Brain: Comparison of Acetylcholine, Nicotine, and α-Bungarotoxin," *Mol. Pharmacol.* 30: 427-437 (1986)
	128	Matter-Sadzinski *et al.*, "Neuronal specificity of the α7 nicotinic acetylcholine receptor promoter develops during morphogenesis of the central nervous system," *EMBO J.* 11: 4529-4538 (1992)
	129	Maue *et al.*, "Neuron-Specific Expression of the Rat Brain Type II Sodium Channel Gene Is Directed by Upstream Regulatory Elements," *Neuron* 4: 223-231 (1990)
	130	Melissari *et al.*, "Mitral valve prolapse in a case of Marfan syndrome with congenital cardiac disease, chronic obstructive pulmonary disease and schizophrenia," *Pathologica* 87: 78-81 (1995)

Examiner: /John Ulm/	Date Considered: 04/03/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JU/

FORM PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VARD-07989	Serial No.: 10/723,940
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))	Applicant: Sherry Leonard *et al.*	
	Filing Date: 11/26/2003	Group Art Unit: 1649

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	131	Miller *et al.*, "A simple salting out procedure for extracting DNA from human nucleated cells," *Nucl. Acids Res.* 16: 1215 (1988)
	132	Miller and Rosman, "Improved Retroviral Vectors for Gene Transfer and Expression," *BioTechniques* 7: 980-990 (1992)
	133	Miller and Freeman, "The Activity of Hippocampal Interneurons and Pyramidal Cells During The Response of the Hippocampus to Repeated Auditory Stimuli," *Neurosci.* 69: 371-381 (1995)
	134	Mizushima and Nagata, "pEF-BOS, a powerful mammalian expression vector," *Nucl. Acids. Res.* 18:5322 (1990)
	135	Nagamoto *et al.*, "Sensory Gating in Schizophrenics and Normal Controls: Effects of Changing Stimulation Interval," *Biol. Psychiat.* 25: 549-561 (1989)
	136	Nagamoto *et al.*, "Gating of Auditory P50 in Schizophrenics: Unique Effects of Clozapine," *Biol. Psychiat.* 40: 181-188 (1996)
	137	Newland *et al.*, "Functional and non-functional isoforms of the human muscle acetylcholine receptor," *J. Physiol.* 489: 767-778 (1995)
	138	Nielsen *et al.*, "Peptide nucleic acids (PNAs): Potential anti-sense and anti-gene agents," *Anticancer Drug Des.* 8:53-63 (1993)
	139	Orr-Urtreger *et al.*, "Cloning and Mapping of the Mouse α7-Neuronal Nicotinic Acetylcholine Receptor," *Genomics* 26: 399-402 (1995)
	140	Ott, *Analysis of Human Genetic Linkage*, Johns Hopkins University Press, Baltimore (1991)
	141	Ott, "Computer-simulation methods in human linkage analysis," *Proc. Natl. Acad. Sci. U.S.A.* 86: 4175-2178 (1989)
	142	Patrick *et al.*, "Molecular Biology of Nicotinic Acetylcholine Receptors," *Ann. NY Acad. Sci.* 505: 194 (1987)
	143	Pauly *et al.*, "Glucocorticoid Regulation of Sensitivity to Nicotine," in *The Biology of Nicotine: Current Research Issues*, Lippiello et al. (eds.), pp. 121-139, Raven Press, New York (1992)
	144	Peng *et al.*, "Human α7 Acetylcholine Receptor: Cloning of the α7 Subunit from the SH-SY5Y Cell Line and Determination of Pharmacological Properties of Native Receptors and Functional α7 Homomers Expressed in *Xenopus* Oocytes," *Mol. Pharm.* 45: 546-554 (1994)
	145	Pulver *et al.*, "Follow-Up of a Report of a Potential Linkage for Schizophrenia on Chromosome 22q12-q13.1: Part 2," *Am. J. Med. Genet.* 54: 44-50 (1994)
	146	Risch, "Genetic Linkage and Complex Diseases, With Special Reference to Psychiatric Disorders," *Genet. Epidemiol.* 7: 3-16 (1990)
	147	Rollins *et al.*, "Cellular Localization of α-Bungarotoxin Binding and α7 mRNA in the Hippocampus Related to Auditory Gating in the Awake, Behaving Rat," *Soc. Neurosci. Abst.* 22: 1272 (1996)
	148	Saksela *et al.*, "Human immunodeficiency virus type 1 mRNA expression in peripheral blood cells predicts disease progression independently of the numbers of $CD4^+$ lymphocytes," *Proc. Natl. Acad. Sci. U.S.A.* 91: 1104-1108 (1994)
	149	Saksela *et al.*, "High Viral Load in Lymph Nodes and Latent Human Immunodeficiency Virus (HIV) in Peripheral Blood Cells of HIV-1 Infected Chimpanzees," *J. Virol.* 67: 7423-7427 (1993)
	150	Sambrook *et al.*, *Molecular Cloning: A Laboratory Manual*, 2nd ed., pp. 7.39-7.52, 9.31-9.58, 16.6-16.15, Cold Spring Laboratory Press, New York (1989)
	151	Samulski *et al.*, "A Recombinant Plasmid from Which an Infectious Adeno-Associated Virus Genome Can Be Excised *In Vitro* and Its Use To Study Viral Replication," *J. Virol.* 61: 3096-3101 (1987)
	152	Samulski *et al.*, "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression," *J. Virol.* 63: 3822-3828 (1989)
	153	Sauerwald *et al.*, "The 5'-Flanking Region of the Synapsin I Gene," *J. Biol. Chem.* 265: 14932-14937 (1990)
	154	Schmid, "Alu: Structure, Origin, Evolution, Significance and Function of One-Tenth of Human DNA," *Prog. Nucl. Acid Res.* 53: 283-319 (1996)
	155	Schoepfer *et al.*, "Brain α-Bungarotoxin Binding Protein cDNAs and MAbs Reveal Subtypes of This Branch of the Ligand-Gated Ion Channel Gene Superfamily," *Neuron* 5: 35-48 (1990)

Examiner: /John Ulm/	Date Considered: 04/03/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JU/

FORM PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VARD-07989	Serial No.: 10/723,940
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))	Applicant: Sherry Leonard *et al.*	
	Filing Date: 11/26/2003	Group Art Unit: 1649

		OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)
	156	Séguéla *et al.*, "Molecular Cloning, Functional Properties, and Distribution of Rat Brain α7: A Nicotinic Cation Channel Highly Permeable to Calcium," *J. Neurosci.* 13: 596-604 (1993)
	157	Sham *et al.*, "Segregration analysis of complex phenotypes: an application to schizophrenia and auditory P300 latency," *Psychiat. Genet.* 4: 29-38 (1994)
	158	Siegel *et al.*, "Deficits in Sensory Gating in Schizophrenic Patients and Their Relatives, Evidence Obtained With Auditory Evoked Responses," *Arch. Gen. Psychiat.* 41: 607-612 (1984)
	159	Silverman *et al.*, "Evidence of a Locus for Schizophrenia and Related Disorders on the Short Arm of Chromosome 5 in a Large Pedigree," *Am. J. Med. Genet.* 67: 162-171 (1996)
	160	Sirota *et al.*, "Schizophrenia and Marfan Syndrome," *Br. J. Psychiat.* 157: 433-436 (1990)
	161	Spitzer *et al.*, "Research Diagnostic Criteria, Rationale and Reliability," *Arch. Gen. Psychiat.* 35: 773-782 (1978)
	162	Stratford-Perricaudet *et al.*, "Widespread Long-term Gene Transfer to Mouse Skeletal Muscles and Heart," *J. Clin. Invest.* 90: 626-630 (1992)
	163	Tsuang *et al.*, "Long-term Outcome of Major Psychoses I. Schizophrenia and Affective Disorders Compared with Psychiatrically Symptom-Free Surgical Conditions," *Arch. Gen. Psychiat.* 36: 1295-1301 (1979)
	164	Tsuang *et al.*, "Genotypes, Phenotypes, and the Brain, A Search for Connections in Schizophrenia," *Brit. J. Psychiat.* 163: 299-307 (1993)
	165	Uetsuki *et al.*, "Isolation and Characterization of the Human Chromosomal Gene for Polypeptide Chain Elongation Factor-1α," *J. Biol. Chem.* 264:5791 (1989)
	166	Ulmer *et al.*, "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," *Science* 259: 1745-1748 (1993)
	167	Vinogradova *et al.*, "Do Semantic Priming Effects Correlate with Sensory Gating in Schizophrenia," *Biol. Psychiat.* 39: 821-824 (1996)
	168	Vinogradova, in *The Hippocampus 2: Neurophysiology and Behavior*, Issacson and Pribram (eds.), pp. 3-69, Plenum Press, New York, New York (1975)
	169	von Heijne, "A new method for predicting signal sequence cleavage sites," *Nuc. Acids Res.* 14: 4683-4690 (1986)
	170	Voss *et al.*, "The role of enhancers in the regulation of cell-type-specific transcriptional control," *Trends Biochem. Sci.* 11:287-289 (1986)
	171	Wada *et al.*, "Distribution of Alpha2, Alpha3, Alpha4, and Beta2 Neuronal Nicotinic Receptor Subunit mRNAs in the Central Nervous System: A Hybridization Histochemical Study in the Rat," *J. Compar. Neurol.* 284: 314-335 (1989)
	172	Waldo *et al.*, "Codistribution of a Sensory Gating Deficit and Schizophrenia in Multi-affected Families," *Psychiat. Res.* 39: 257-268 (1991)
	173	Waldo *et al.*, "Auditory sensory gating, hipppocampal volume, and catecholamine metabolism in schizophrenics and their siblings," *Schizophr. Res.* 12: 93-106 (1991)
	174	Wang *et al.*, "Evidence for a susceptibility locus for schizophrenia on chromosome 6pter-p22," *Nature Genet.* 10: 41-46 (1995)
	175	Williams *et al.*, "Introduction of foreign genes into tissues of living mice by DNA-coated microprojectiles," *Proc. Natl. Acad. Sci. U.S.A.* 88: 2726-2730 (1991)
	176	Wilson *et al.*, "Habituation of Human Limbic Neuronal Response to Sensory Stimulation," *Exp. Neurol.* 84: 74-97 (1984)
	177	Wilson *et al.*, "Hepatocyte-directed Gene Transfer in Vivo Leads to Transient Improvement of Hypercholesterolemia in Low Density Lipoprotein Receptor-deficient Rabbits," *J. Biol. Chem.* 267: 963-967 (1992)
	178	Wonnacott, "α-Bungarotoxin Binds to Low-Affinity Nicotine Binding Sites in Rat Brain," *J. Neurochem.* 47: 1706-1712 (1986)
	179	Wu and Wallace, "The Ligation Amplification Reaction (LAR) -- Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," *Genomics* 4:560-569 (1989)
	180	Wu and Wu, "Receptor-mediated Gene Delivery and Expression in Vivo," *J. Biol. Chem.* 263: 14621-14624 (1988)

Examiner: /John Ulm/	04/03/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JU/

FORM PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VARD-07989	Serial No.: 10/723,940
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))	Applicant: Sherry Leonard *et al.*	
	Filing Date: 11/26/2003	Group Art Unit: 1649

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	181	Wu and Wu, "Receptor-mediated *in Vitro* Gene Transformation by a Soluble DNA Carrier System," *J. Biol. Chem.* 262: 4429-4432 (1987)
	182	Zhang *et al.*, "Neuronal Acetylcholine Receptors That Bind α-Bungarotoxin with High Affinity Function as Ligand-Gated Ion Channels," *Neuron* 12: 167-177 (1994)
	183	Anand and Lindstrom, "Nucleotide sequence of the human nicotinic acetylcholine receptor β2 subunit gene," *Nuc. Acids Res.* 18: 4272 (1990)
	184	Chini *et al.*, "Molecular Cloning and Chromosomal Localization of the Human α7-Nicotinic Receptor Subunit Gene (CHRNA7)," *Genomics* 19: 379-381 (1994)
	185	Deneris *et al.*, "Primary Structure and Expression of β2: A Novel Subunit of Neuronal Nicotinic Acetylcholine Receptors," *Neuron* 1: 45-54 (1988)
	186	Doucette-Stamm *et al.*, "Cloning and Sequence of the Human α7 Nicotinic Acetylcholine Receptor," *Drug Dev. Res.* 30: 252-256 (1993)
	187	Fornasari *et al.*, "Molecular cloning of human neuronal nicotinic receptor α3-subunit," *Neurosci. Lett.* 111: 351-356 (1990)
	188	Fornasari *et al.*, "Structural and Functional Characterization of the Human α3 Nicotinic Subunit Gene Promoter," *Mol. Pharmacol.* 51: 250-261 (1997)
	189	Garcia-Guzman *et al.*, "α-Bungarotoxin-sensitive Nicotinic Receptors on Bovine Chromaffin Cells: Molecular Cloning, Functional Expression and Alternative Splicing of the α7 Subunit," *Eur. J. Neuorosci.* 7: 647-655 (1995)
	190	GenBank Accession No. X70297 (1993)
	191	GenBank Accession No. Z58126 (1995)
	192	Breese *et al.*, "Comparison of the Regional Expression of Nicotinic Acetylcholine Receptor α7 mRNA and [^{125}I]-α-bungarotoxin binding in Human Postmortem Brain," *J. Comp. Neurol.* 387: 385-398 (1997)
	193	Leonard *et al.*, "Linkage of a chromosome 15 locus to a neurophysiological deficit in schizophrenia," *Am. J. Human Genet.* 59: A225 (1996)
	194	Leonard *et al.*, "Genomic Structure of the Human α7 Neuronal Nicotinic Acetylcholine Receptor Subunit," *Abstracts, Society for Neuroscience*, 27th Annual Meeting, October 25-30 (1997)
	195	Freedman *et al.*, "Linkage of a neurophysiological deficit in schizophrenia to a chromosome 15 locus," *Proc. Natl. Acad. Sci. U.S.A.* 94: 587-592 (1997)
	196	Logel *et al.*, "Expression of High and Low Affinity Neuronal Nicotinic Receptors in Tissues of Neural Crest Origin," *Abstracts, Society for Neuroscience*, 27th Annual Meeting, October 25-30 (1997)
	197	Breese *et al.*, "Abnormal Regulation of High Affinity Nicotinic Receptor Binding in Schizophrenics," *Abstracts, Society for Neuroscience*, 27th Annual Meeting, October 25-30 (1997)
	198	Gault *et al.*, "Contig construction across the 15q14 schizophrenia linkage region and candidate gene characterization of the partially duplicated α7 nicotinic receptor," *Am. J. Human Genet.* 63: A249 (1998)
	199	Leonard *et al.*, "Additional evidence for a chromosome 15 locus in schizophrenia: Analysis of affected sibpairs from the NMH genetics initiative," *Am. J. Human Genet.* 63: A297 (1998)
	200	Zetterström *et al.*, "Polymorphisms at the Calcitonin/CGRP-α Gene Locus: Investigation of Possible Associations with Neurological or Psychiatric Disease," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998)
	201	Drebing *et al.*, "Expression of the Human α7 Neuronal Nicotinic Acetylcholine Receptor and a Partial Gene Duplication," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998)
	202	Leonard *et al.*, "Genomic Organization and Partial Duplication of the Human α7 Neuronal Nicotinic Acetylcholine Receptor Subunit Gene," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998)
	203	Dudek *et al.*, "Expression in Human Brain of Novel Exons Associated with a Partial Duplication of the α7 Neuronal Nicotinic Receptor," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998)
	204	Breese *et al.*, "Abnormal Regulation of the High Affinity Nicotinic Receptors in Schizophrenia," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998)
	205	Lee *et al.*, "The Effect of Nicotine and Haloperidol on High Affinity Nicotinic Receptors and Dopamine D2 Receptors in the Rat Brain," *Abstracts, Society for Neuroscience*, 28th Annual Meeting, November 7-12 (1998)

Examiner: /John Ulm/	Date Considered: 04/03/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JU/

FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VARD-07989	Serial No.: 10/723,940
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))		Applicant: Sherry Leonard *et al.*	
		Filing Date: 11/26/2003	Group Art Unit: 1649

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	206	Adler *et al.*, "Schizophrenia, Sensory Gating, and Nicotinic Receptors," *Schizophrenia Bulletin* 24: 189-202 (1998)
	207	Leonard *et al.*, "Further Investigation of a Chromosome 15 Locus in Schizophrenia: Analysis of Affected Sibpairs From the NIMH Genetics Initiative," *Am. J. Med. Genet.* 81: 308-312 (1998)
	208	Gault *et al.*, "Genomic Organization and Partial Duplication of the Human α7 Neuronal Nicotinic Acetylcholine Receptor Gene (CHRNA7), *Genomics* 52: 173-185 (1998)
	209	Leonard *et al.*, "Association of promoter variants in the alpha7 nicotinic acetylcholine receptor subunit gene with an inhibitory deficit found in schizophrenia," *Arch Gen Psychiatry*, 59:1085-1096 (2002)
	210	Gault *et al.*, "Comparison of polymorphisms in the alpha7 nicotinic receptor gene and its partial duplication in schizophrenic and control subjects," *Am J Med Genet B Neuropsychiatr Genet*, 123:39-49 (2003)
	211	Leonard, "Consequences of low levels of nicotinic acetylcholine receptors in schizophrenia for drug development, *Drug Development Research*, 60:127-136 (2003)
	212	Mexal *et al.*, Differential modulation of gene expression in the NMDA postsynaptic density of schizophrenic and control smokers," *Mol Brain Res*, 139:317-332 (2005)

Examiner: /John Ulm/	Date Considered: 04/03/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.